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OCT 03 2006

## REMARKS

This is an amendment with request for continued examination (RCE) filed in response to the final Office Action dated April 19, 2006.

### I. Claim Changes

The independent composition claims 10, 16, and 21 have been amended to further distinguish them from the cited prior art by including the feature that the bioactive glass particles include CaO and P<sub>2</sub>O<sub>5</sub> in such amounts that a layer of hydroxyapatite forms on the particles in aqueous media. This is an essential bioactive glass characteristic, which can be confirmed by consulting pages 1 to 3 of applicants' specification. The particular wording for this limitation used in claims 10, 16, and 21 has been taken from page 3, lines 2 and 3 of the applicants' U.S. specification.

The broad molar ratio of calcium to phosphorus has also been included in the dependent claims from page 3, lines 27 to 31.

### II. Indefiniteness Rejection

Claims 13, 14, and 19 were rejected under 35 U.S.C. 112, second paragraph, as indefinite.

Claims 14 and 19 have been canceled, obviating their rejection on these grounds.

Claim 13 has been amended to delete the subject matter regarding the toxic metal cations and thus now avoids the reason for its rejection as indefinite.

For the foregoing reasons and because of the changes in claim 13, withdrawal of the rejection of amended claim 13 under 35 U.S.C. 112, second paragraph, is respectfully requested.

### **III. Anticipation Rejection based on Shimono, et al**

Claims 10 to 14 and 21 to 24 were rejected under 35 U.S.C. 102 (b) as anticipated by U.S. Patent 5,290,544 to Shimono, et al.

Shimono, et al, do disclose a soluble glass containing silver ions, which can be used as a preservative for cosmetic preparations. Basically the soluble glass of Shimono is a delivery vehicle for the silver ions, which have been used since biblical times to preserve food and drink (column 2, lines 3 to 14). Without the silver ions or another toxic cation the glasses of Shimono, et al, would not have any anti-microbial action.

Applicants' method claims have been amended to limit the bioactive glass particles to a glass that includes CaO and P<sub>2</sub>O<sub>5</sub> in amounts such that a molar ratio of calcium to phosphorus is greater than 2 and a layer of hydroxyapatite forms on the surface of the particles in aqueous media. Basis for these limitations appears on page 3, lines 1 to 3, and lines 27 to 31, of applicants' originally filed U.S. specification.

In contrast, the soluble glasses disclosed by Shimono are not bioactive

glasses, which fit the limitation added in claim 10. First, US '544 does not use the term "bioactive glass". Next, of the claims only claims 4 and 6 are relevant and these claims do not limit the glass of Shimono, et al, to a glass that includes CaO and P<sub>2</sub>O<sub>5</sub> in amounts such that a molar ratio of calcium to phosphorus is greater than 2 and a layer of hydroxyapatite forms on the surface of the particles in aqueous media. Only examples 2 and 4 of US '544 contain both CaO and P<sub>2</sub>O<sub>5</sub> and these examples do not satisfy the condition now present in all independent claims that the molar ratio of calcium to phosphorus is greater than 2.

Various prior art references, for example U.S. Patent 5,074,916, issued December 24, 1991, confirm that the features of the bioactive glass included in the independent claims by the above changes are part of the accepted understanding in the art regarding the nature of bioactive glasses. In the 'Description of the Prior art' section of this patent it states that bioactive glass must contain a substantial amount of sodium oxide and calcium oxide as well as phosphorus oxide in addition to SiO<sub>2</sub>. **It must have a comparatively high ratio of calcium to phosphorus.**

It is well established that each and every limitation of a claimed invention must be disclosed in a single prior art reference in order to be able to reject the claimed invention under 35 U.S.C. 102 (b) based on the disclosures in the single prior art reference. See M.P.E.P. 2131 and also the opinion in *In re Bond*, 15 U.S.P.Q. 2nd 1566 (Fed. Cir. 1990).

Since Shimono, et al, do not disclose a method of preserving a preparation with a bioactive glass that includes CaO and P<sub>2</sub>O<sub>5</sub> in amounts such

that a molar ratio of calcium to phosphorus is greater than 2 and a layer of hydroxyapatite forms on the surface of the particles in aqueous media, none of amended claims 10 to 13 and 21 to 24 can be rejected as anticipated by Shimono, et al.

For the foregoing reasons and because of the changes in the independent claims, withdrawal of the rejection of amended claims 10 to 13 and 21 to 24 under 35 U.S.C. 102 (b) as anticipated by Shimono, et al, is respectfully requested.

#### **IV. Obviousness Rejection based on Shimono, et al, and Greenspan**

Claims 15 and 20 were rejected under 35 U.S.C. 103 (a) over U.S. Patent 5,290,544 issued to Shimono, et al, in view of International Patent Application WO 98/11853 filed by Greenspan.

Claims 15 and 20 limit the bioactive glass composition used in the method claimed in the independent method claims 10 and 16 to the glass composition of claim 2 of Greenspan.

However one skilled in the art would not be motivated by the disclosures in US '544 and WO '853 to use the glass composition of claim 2 of Greenspan as a preservative for a cosmetic and/or pharmaceutical composition. From a different standpoint, there is not the slightest suggestion in either Greenspan or US '544 that the glass compositions of Shimono, et al, should be replaced by the glass composition of claim 2 of Greenspan. The molar ratio of calcium to

phosphorus is not identified by either reference as a result effective variable for manipulation to provide protection of a cosmetic composition from microbial action.

The features of the glass compositions used by Shimono, et al, have been described above in connection with the anticipation rejection. The critical ratio of calcium to phosphorus has not been disclosed in Shimono, et al, as a result effective variable that can be manipulated to provide protection from microbial action. The compositions of Shimono are not limited to any particular calcium to phosphorus ratio.

None of applicants' claims are *prima facie* obvious under 35 U.S.C. 103  
(a) from a combination of Shimono, et al, and Greenspan.

Greenspan discloses a composition for accelerated healing of wounds that necessarily comprises bioactive glass particles and at least one topical antibiotic. Greenspan also discloses a method of treating a wound with their composition.

There is nothing in Greenspan that suggests that the antimicrobial action can be obtained without the antibiotic. However the method claimed in method claim 15 does not include adding an antibiotic because according to claim 15 bioactive glass particles are added in the method; an antibiotic is not mentioned. The same is true of composition claim 20. Claim 16 does not mention an antibiotic.

At best a combination of Greenspan with Shimono, et al, would suggest adding an antibiotic to the glass compositions of Shimono, et al, to increase their

effectiveness in preserving the cosmetic composition. However there is no suggestion in Greenspan that the glass composition of claim 2 of this WO reference could replace the glass compositions of Shimono, et al, in the cosmetic and provide effective protection from microbial action.

It is well established by many U. S. Court decisions that to reject a claimed invention under 35 U.S.C. 103 there must be some hint or suggestion in the prior art of the modifications of the disclosure in a prior art reference or references used to reject the claimed invention, which are necessary to arrive at the claimed invention. For example, the Court of Appeals for the Federal Circuit has said:

"Rather, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant...Even when obviousness is based on a single reference there must be a showing of a suggestion of motivation to modify the teachings of that reference." *In re Kotzab*, 55 U.S.P.Q. 2<sup>nd</sup> 1313 (Fed. Cir. 2000). See also M.P.E.P. 2141

There is no suggestion in Greenspan that the bioactive glass of claim 2 of that WO reference would be effective in preserving a cosmetic composition or as an antimicrobial agent --- without the antibiotic required by claim 1.

Second neither Greenspan nor Shimono, et al, disclose or suggest the result-effective variable, namely the molar ratio of calcium to phosphorus, which can be manipulated to maximize protection from microbial action. This feature or limitation is present in the subject matter of claims 15 and 20, because it is present in the amended claims 10 and 16 on which they depend.

Optimum preservative effect can be provided only if the result-effective variable is optimized. See M.P.E.P. 2144.5. However there is no suggest that the molar ratio of calcium to phosphorus is a result-effective variable in either reference.

Furthermore with respect to claim 16 or 20 there is no suggestion of the negative limitation that the compositions of applicants' claims 20 and 16 do not contain alcohol in either Shimono, et al, or Greenspan. Some of the antibiotics of claim 6 of Greenspan are alcohols. Also example 3 of Shimono ,et al, (column 6) discloses a face power that includes the soluble glass preservative, but also ethanol and glycerol. Thus Shimono, et al, **teach against** this negative limitation in applicants' claims 20 and 16 because they teach that their soluble glass preservative can be included in cosmetic compositions including alcohol.

It is well established that a reference that contains teaching that would lead one skilled in the art away from a claimed invention should not be combined with another reference to reject the claimed invention.

"In determining whether such a suggestion [of obviousness] can fairly be gleaned from the prior art ..It is indeed pertinent that these references teach against the present invention. Evidence that supports, rather than negates, patentability must be fairly considered." *In re Dow Chemical Co.*, 837 F.2nd 469,473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988)

Claims 16 and 20 exclude alcohols. But contrary to this claim 6 of Greenspan teaches that the antibiotic of Greenspan can be chloramphenicol, which according to the free Internet encyclopedia is an alcohol. If that were not enough, example 3 of Shimono, et al, teaches it is acceptable to include ethanol.

Furthermore although Shimono, et al, requires that an alcohol is necessarily present in all embodiments of their compositions, the individual embodiments disclosed in a prior art reference are also valid disclosures of prior art. This principle is often used in supporting anticipation rejections. The prior art references do teach some embodiments including alcohols and thus teach the opposite from the claimed invention in the case of those embodiments.

No embodiments of the compositions of claim 16 can contain any alcohol in contrast to Shimono, et al.

In addition, the term "alcohol" in claim 16 presumably should be given its broadest reasonable interpretation. Some of the antibiotics of claim 6 of Greenspan are alcohols, as explained above.

For the foregoing reasons withdrawal of the rejection of claims 15 and 20 under 35 U.S.C. 103 (a) over U.S. Patent 5,290,544 issued to Shimono, et al, in view of International Patent Application WO 98/11853 filed by Greenspan, is respectfully requested.

#### **V. Obviousness Rejection based on Shimono and Various Scientific Journal Articles**

Claims 16 to 19 were rejected under 35 U.S.C. 103 (a) over U.S. Patent 5,290,544 issued to Shimono, et al, in view of Yamanaka, et al, Chem. Materials 4(3), pp. 495-497 (1992); Wu, et al, Chem. Materials 5(1), pp. 115 - 120 (1993);

and Wang, et al., Anal. Chem. 65 (19), pp. 2671- 2675 (1993).

Shimono, et al, has been discussed in greater detail above and the discussion will not be repeated here.

The secondary references, Yamanaka, et al; Wu, et al; and Wang, et al, do not supply the necessary hint or suggestion of the added limitations in claim 16, namely that the bioactive glass particles in the composition include CaO and P<sub>2</sub>O<sub>5</sub> in amounts such that a molar ratio of calcium to phosphorus is greater than 2 and a layer of hydroxyapatite forms on the surface of the particles in aqueous media.

Thus a case of *prima facie* obviousness of claim 16 and the dependent claims cannot be established by combination of the secondary references with Shimono, et al, since they do not suggest the added limitations.

For the foregoing reasons withdrawal of the rejection of claims 16 to 19 under 35 U.S.C. 103 (a) over U.S. Patent 5,290,544 issued to Shimono, et al, in view of Yamanaka, et al, Chem. Materials 4(3), pp. 495-497 (1992); Wu, et al, Chem. Materials 5(1), pp. 115 - 120 (1993); and Wang, et al., Anal. Chem. 65 (19), pp. 2671- 2675 (1993) is respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the

case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,



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